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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,178	07/08/2003	Dennis M. Brown	A-71462/RFT/THR (468899-3)	1122

7590 10/24/2005

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EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/616,178	Applicant(s) BROWN, DENNIS M.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7 and 15-22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 4 is/are allowed.
- 6) ☒ Claim(s) 5 -7, 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/6/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 3-7, 15-22 are pending.

Claim Rejections - 35 USC § 103

The rejection of claims 5-7, 15-21 still stands over Brana et al US 5420137 and Brana II 5552544.

Examiner is now also including claim 22.


Applicants arguments are not found to be convincing.

The rejection has been modified.

Drug development and Industrial pharmacy (1995) Torres et al clearly teaches the amonafide 2HCl and also that it is highly hygroscopic. (see last paragraph on page 186).

Also see the conclusions that amonafide 2HCl has bad flow properties and low compressibility, along with the fact that it is hygroscopic, would make it obvious and convenient to make its aqueous solution to make injectable solution.

Brana'137 teaches the injectable solutions see example E in column 3 of the reference.

Example E		
Preparation of amonafide injection concentrate as lyophilisate		
	Amonafide 2HCl	2.992 kg
	NaOH, 5 m	1.958 kg
	Water for injection ad	20.000 kg
The solution was sterilized by filtration and subsequently dispensed in 2 ml portions into vials of glass type I (brown glass) and freeze-dried. The pH of the reconstituted solution was 5.5 ± 0.5 , the osmolality was		

It uses water for the injection ad. It also uses the NaOH. Even though it teaches the monohydrochloride the dihydrochloride which is hygroscopic can obviously be made in the same way.

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The pH of the solution is 5.5 + or - .5 which comes to about 6.

Thus the process for the monohydrochloride is given, one of skill in the art would have found it obvious to use the same process for the 2HCl amonafide.

The limitations of claims 15-22 are clearly met.

The Brana '137 teaches a process of making the amonafide hydrochloride by adding hydrochloride dropwise and stirring vigorously. Since there are 2 ammonium groups, it would be obvious that if one stirred it for a longer time it would yield the dihydrochloride salt.

Conclusion

Only claims 3 and 4 are found to be allowable since the prior art does not teach using the ammonium formate to make it.

Claims 15-22 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
October 20, 2005

R. Desai
10/20/05